1.0 INTRODUCTION

Note: *Click here* for lessons learned *that may apply* to the requirements contained in this LIR.

1.1 Background

The requirements contained in this Laboratory implementation requirements (LIR) document address the development of non-nuclear facilities safety bases that identify and control the hazards and the risk posed by these facilities to the worker, the public, and the environment. The facility hazard category defines the type and rigor of safety basis documentation and the approval authority for this documentation. Specifically, a facility with a greater hazard potential requires a more detailed safety analysis, a broader and more formal set of hazard controls, and a higher level of management approval than a facility with lesser hazards.

Requirements for safety basis documentation for non-nuclear facilities are derived from industry standards, the U.S. Department of Energy (DOE), Laboratory performance requirements, and other LIRs. A non-nuclear facility safety basis represents a documented acknowledgement by line management official(s) affirming that the facility risks are understood and that the hazard controls protect the worker, the public, and the environment from these risks. This acknowledgement is based on an evaluation that demonstrates that hazards and the potential consequences from these hazards are fully understood and that hazard controls provide the required protection.

The requirements contained in the LIR will be effective upon the revision issue date. This LIR complements the requirements contained in LIR 300-00-05, *Facility Hazard Categorization* and LIR 300-00-06, *Nuclear Facility Safety Authorization Basis.*

1.2 In This Document

2.0 PURPOSE

This LIR defines the requirements that must be implemented for developing a safety basis that is required for operating a non-nuclear facility.

> **Guidance Note:** In addition to requirements for analyzing hazards and determining hazard controls, this LIR establishes approval authority for the safety basis documents based on facility hazard categorization which is determined in accordance with LIR 300-00-05, *Facility Hazard Categorization.*

3.0 SCOPE AND APPLICABILITY

The requirements contained in this LIR will apply to all organizations conducting operations in non-nuclear facilities, constructing a new non-nuclear facility, or performing a facility upgrade or modification to an existing non-nuclear facility.

4.0 DEFINITIONS

Accelerator Facility. A structure with an operating accelerator or modules thereof, including injectors, targets, beam dumps, detectors, experiments, experiment halls, etc. Per DOE O 420.2B, *Safety of Accelerator Facilities*, the following are excluded from the requirements of DOE O 420.2B:

- Unmodified commercially available units that are acceptable for industrial applications, including (but not limited to) electron microscopes, ion implant devices, and x-ray generators;
- Accelerator facilities not capable of creating a radiological area as defined in Title 10 Code of Federal Regulations 835, “Occupational Radiation Protection”;
- Naval Nuclear Propulsion Program accelerators covered under Executive Order 12344 (42 United States Code 7158 Note);
- Non-medical x-ray devices with the capability of accelerating particles to energies not greater than 10 MeV, which are operated in accordance with American National Standards Institute (ANSI) N43.3-1993 *General Radiation Safety –Installations Using Non-Medical X-Ray and Sealed Gamma-Ray Sources, Energies Up to 10 MeV,* or in accordance with another applicable consensus standard as directed by the cognizant field element manager/NNSA field manager;
- Low-voltage neutron generators incapable of creating a “high-radiation” area as defined in 10 CFR 835, “Occupational Radiation Protection: Final Rule”, and which are operated in accordance with National Council on Radiation Protection Report 72-1983, *Radiation Protection and Measurements for Low-Voltage Neutron Generators*, or in accordance with another applicable consensus standard as directed by the cognizant DOE/NNSA field manager. For the purpose of this Order, a low-voltage neutron generator is defined

as a bench-top scale, single-purpose device generating neutrons by accelerating deuterons or tritons into targets through a maximum accelerating potential not greater than 600 kV.

- Entire DOE/NNSA accelerator facilities or modules thereof when and only when accelerators and their operations involve or produce a sufficient inventory of fissionable materials to create the potential for criticality.

Biosafety. (definitions for biosafety levels are taken directly from Reference 24):

- **Biosafety Level 1** (BSL-1) is suitable for work involving well-characterized agents not known to consistently cause disease in healthy adult humans, and of minimal potential hazard to laboratory personnel and the environment. The laboratory is not necessarily separated from the general traffic patterns in the building. Work is generally conducted on open bench tops using standard microbiological practices. Special containment equipment or facility design is neither required nor generally used. Laboratory personnel have specific training in the procedures conducted in the laboratory and are supervised by a scientist with general training in microbiology or a related science.

- **Biosafety Level 2** (BSL-2) is similar to Biosafety Level 1 and is suitable for work involving agents of moderate potential hazard to personnel and the environment. It differs from BSL-1 in that (1) laboratory personnel have specific training in handling pathogenic agents and are directed by competent scientists; (2) access to the laboratory is limited when work is being conducted; (3) extreme precautions are taken with contaminated sharp items; and (4) certain procedures in which infectious aerosols or splashes may be created are conducted in biological safety cabinets or other physical containment equipment.

- **Biosafety Level 3** (BSL-3) is applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route. Laboratory personnel have specific training in handling pathogenic and potentially lethal agents, and are supervised by competent scientists who are experienced in working with these agents. All procedures involving the manipulation of infectious materials are conducted within biological safety cabinets or other physical containment devices, or by personnel wearing appropriate personal protective clothing and equipment. The laboratory has special engineering and design features.

- **Biosafety Level 4** (BSL-4) is required for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease. Agents with a close or identical antigenic relationship to Biosafety Level 4 agents are handled at this level until sufficient data are obtained either to confirm continued work at this level, or to work with them at a lower level. Members of the laboratory staff have specific and thorough training in handling extremely hazardous infectious agents and they understand the primary and secondary containment functions of the standard and special practices, the containment equipment, and the laboratory design characteristics. They are supervised by competent scientists who are trained and

experienced in working with these agents. Access to the laboratory is strictly controlled by the laboratory director. The facility is either in a separate building or in a controlled area within a building, which is completely isolated from all other areas of the building. A specific facility operations manual is prepared or adopted.

Within work areas of the facility, all activities are confined to Class III biological safety cabinets, or Class II biological safety cabinets used with one-piece positive pressure personnel suits ventilated by a life support system. The Biosafety Level 4 laboratory has special engineering and design features to prevent microorganisms from being disseminated into the environment.

Emergency Response Planning Guideline (ERPG). Values intended to provide estimates of concentration ranges where one reasonably might anticipate observing adverse effects as described in the definitions for ERPG-1, ERPG-2, and ERPG-3 as a consequence of exposure to the specific substance.

- ERPG-1 is the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hour without experiencing other than mild transient adverse health effects or perceiving a clearly defined, objectionable odor.

- ERPG-2 is the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hour without experiencing or developing irreversible or other serious health effects or symptoms which could impair an individual's ability to take protective action.

- ERPG-3 is the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hour without experiencing or developing life-threatening health effects.

Explosives Facility. A facility which develops, tests, handles, or processes explosives or assemblies containing explosives.

Facility Safety Analysis (FSA). A safety analysis and determination of controls for non-nuclear high and moderate hazard category facilities.

Facility Safety Plan (FSP). A document, or a collection of referenced documents, which addresses the facility and tenant operations limits and configuration. (See LAUR-98-2837, Section 5.5, LIG 240-01-10.1, “Facility Safety Plan,” and LPR 240-01-00 for further details)

Graded Approach. The process of ensuring that the level of analysis, documentation, and actions used to implement requirements are commensurate with:

1. The relative importance to safety, safeguards, and security;
2. The magnitude of any hazard involved;
3. The life cycle stage of the facility;
4. The programmatic mission of the facility;

5. The particular characteristics of the facility;
6. The relative importance of radiological and nonradiological hazards; and
7. Any other relevant factor.

(Ref: 10 CFR 830.3(a)) (Ref: DOE-STD-3009-94, page xxiv)

Hazard. A source of danger (i.e., material, energy source, or operation) with the potential to cause illness, injury, or death to a person or damage to a facility or to the environment (without regard to the likelihood or credibility of accident scenarios or consequence mitigation). (Ref: 10 CFR 830.3(a))

Hazard Analysis (HA). The determination of material, system, process, and plant characteristics that can produce undesirable consequences, followed by the assessment of hazardous situations associated with a process or activity. Largely qualitative techniques are used to pinpoint weaknesses in design or operation of the facility that could lead to accidents. The hazards analysis examines the complete spectrum of potential accidents that could expose members of the public, onsite workers, facility workers, and the environment to hazardous materials. (Ref: DOE-STD-3009-94, CN2, page xxv)

Hazard controls. Measures to eliminate, limit, or mitigate hazards to workers, the public, or the environment, including

(1) Physical, design, structural, and engineering features;

(2) Safety structures, systems, and components;

(3) Safety management programs;

(4) Technical safety requirements; and

(5) Other controls necessary to provide adequate protection from the hazards.

(Ref: 10 CFR 830.3(a))

Involved Worker. A person actively involved in accomplishing the mission of a specific facility. Such a person exercises safety responsibilities, which may differ from program or administrative responsibilities, to the same RDL as is responsible for the safety of the facility; has an equivalent level of safety training as others in the facility (e.g., training on the hazards, FSP, and HCPs); and is protected by the same safety controls (e.g., emergency response plans and communications or alarm systems) as others in the facility.

Management Level (ML). A classification system (i.e. ML-1, ML-2, etc.) for determining the degree of management control applied to facility work (LIG 230-01-02, *Graded Approach for Facility Work*).

Non-nuclear Facility. A facility whose activities involve hazards other than radioactive materials or is not considered a nuclear facility as defined in 10 CFR 830.3.

Nonreactor nuclear facility. Those facilities, activities, or operations that involve, or will involve, radioactive and/or fissionable materials in such form and quantity that a nuclear or nuclear explosive hazard potentially exists to workers, the public, or the environment, but does not include accelerators and their operations and does not include activities involving only incidental use and generation of radioactive materials or radiation such as check and calibration sources, use of radioactive sources in research and experimental and analytical laboratory activities, electron microscopes, and X-ray machines. (10 CFR 830)

Nuclear facility. A reactor or a nonreactor nuclear facility where an activity is conducted for or on behalf of DOE and includes any related area, structure, facility, or activity to the extent required to ensure correct implementation of the requirements contained in 10 CFR 830, "Nuclear Safety Management."

Operational Safety Requirement(s) (OSR). The formal requirements that define the passive or active engineered features, conditions, safe boundaries, management, or administrative controls required to ensure the safe operation of a moderate or high hazard non-nuclear facility.

Readiness Review (RR). A Laboratory and/or National Nuclear Security Administration (NNSA) verification of operational readiness to confirm that the facility (including hardware, procedures, and personnel) is ready to operate and effectively implements applicable Laboratory and NNSA requirements.

Responsible Division Leader (RDL). An individual designated by their line management Associate Director (AD) to assume ultimate responsibility, authority and accountability for a facility, and to ensure the requirements contained in LIR 300-00-06, *Nuclear Facility Safety Basis*, and LIR 300-00-07, *Non-nuclear Facility Safety Basis* are met. (Ref: LIR 280-02-01.2)

Safety Basis (SB). The documented safety analysis and hazard controls that provide reasonable assurance that a DOE nuclear facility can be operated safely in a manner that adequately protects workers, the public, and the environment. (10 CFR 830.3(a))

Guidance Note: Safety basis is a term from 10 CFR 830 but is also used at LANL for non-nuclear facilities and activities.

Safety Basis Change Control. The process or mechanism for keeping a safety basis current by reviewing potential facility or operations changes and taking necessary action.

Safety structures, systems, and components (safety SSCs). Both safety-class structures, systems, and components and safety-significant structures, systems, and components (Ref: 10 CFR 830.3(a)). The set of safety-class structures, systems, and components, and safety-significant structures, systems, and components for a given facility (Ref: DOE-STD-3009-94, page xxvii).

Site Boundary. A well-marked boundary of the property over which the National Nuclear Security Administration (NNSA) and Los Alamos National Laboratory (LANL) (owner and operator, respectively) can exercise strict control without the aid of outside authorities.

Guidance Note: For the purposes of implementing this and other LIR requirements, the LANL site boundary is defined as the geographic boundary within which public access is controlled and activities are governed by NNSA and LANL, and not by local authorities.

Guidance Note: A public road traversing the site is considered to be within the site boundary if, when required, NNSA or LANL has the capability to control the road during accident or emergency conditions. The truck route (East Jemez Rd) is not considered within the LANL site boundary at the time of issuance of this document. Additionally, ongoing land transfer activities may change the site boundary. Questions related to the latest site boundary definition should be addressed to the Safety Basis Office (SBO), PS-4.

Tenant. An individual or organization that occupies space or performs work within a facility in accordance with the Facility Tenant Agreement.

Temporary Emergency Exposure Limit (TEEL). These limits are expressed as four levels (0–3):

- TEEL 0: The threshold concentration below which most people would experience no appreciable risk of health effects.
- TEEL 1: The maximum concentration in air below which it is believed nearly all individuals could be exposed without experiencing anything other than mild transient adverse health effects or perceiving a clearly defined objectionable odor.
- TEEL 2: The maximum concentration in air below which it is believed nearly all individuals could be exposed without experiencing or developing irreversible or other serious health effects or symptoms that could impair their abilities to take protective action.
- TEEL 3: The maximum concentration in air below which it is believed nearly all individuals could be exposed without experiencing or developing life-threatening health effects.

Uninvolved worker. A site worker who does not satisfy the **involved worker** definition.

5.0 PRECAUTIONS AND LIMITATIONS

None

6.0 INDIVIDUAL/ORGANIZATIONAL IMPLEMENTATION REQUIREMENTS

6.1 Associate Director

The associate director (AD) will be responsible for:

- Providing final approval of moderate hazard non-nuclear non-biological facility safety basis documents;
- Providing intermediate approval of high hazard non-nuclear facility safety basis documents;

- Forwarding high hazard non-nuclear safety basis documents through the Safety Basis Office (SBO), PS-4, to NNSA for final approval.

6.2 Responsible Division Leader (RDL)

The RDL will be responsible for:

- Ensuring that trained and competent personnel prepare and manage the safety basis and related processes;
- Ensuring facility workers, including those from tenant organizations, are involved in developing the facility safety basis;
- Establishing and maintaining a formal inventory system to assure the categorization remains valid;
- Reviewing and forwarding the safety basis documents for moderate hazard, high hazard, and accelerator facility to the SBO (PS-4);
- Ensuring that all PS-4 review comments are resolved;
- Ensuring that controlled copies of the approved safety basis documents for moderate hazard, high hazard, and accelerator facilities are distributed to the Safety Basis Office (PS-4), Emergency Management and Response (EM&R), and tenant organizations;
- Establishing a formal change control program for moderate hazard, high hazard, and accelerator facilities;
- Performing a full safety basis review and update within the required intervals;
- Submitting 90% review safety basis documents to the organization responsible for the Emergency Planning Hazards Assessment (EPHA); and
- Requiring project management techniques for the preparation of safety basis documents. LANL project management requirements are given in IMP 352.0, **Project Management**.

  Guidance Note: If a Deputy Responsible Division Leader (DRDL) has been appointed, the DRDL will be responsible to the RDL for those safety basis responsibilities assigned to the DRDL in the individual position description.

6.3 Safety Basis Office (SBO) Leader (PS-4)

The SBO (PS-4) leader will be responsible for:

- Providing institutional interpretation of the requirements contained in this LIR;
- Providing technical assistance in hazard and consequence analyses for safety basis purposes;
- Ensuring that personnel are qualified to conduct quality and technical review of safety basis documents and processes;
- Acting as institutional liaison between Laboratory facilities and the NNSA/LASO for safety basis issues;
- Assisting program offices in coordinating priorities and resources for establishing and maintaining safety bases;

- Reviewing and providing SBO approval of the safety basis documentation for moderate hazard facilities.
- Reviewing the safety basis documentation for high hazard and accelerator facilities. Making recommendations to the RDL and AD regarding the adequacy of safety basis documents in meeting the requirements of this LIR and technical accuracy.

6.4 Tenants

The division leader for a tenant organization will be responsible for:

- Providing assistance in developing the safety basis;
- Training facility workers in the safety basis and hazard controls; and
- Using only controlled copies of safety basis and hazard control documents in facility operations.

7.0 FACILITY IMPLEMENTATION REQUIREMENTS

7.1 All Non-Nuclear Facilities

The following requirements apply to all non-nuclear facilities:

- Implementation of these requirements must be consistent with the requirement contained in LIR 300-00-05, *Facility Hazard Categorization*, which states that "within 60 days (of publishing LIR 300-00-05), the responsible division leaders (RDLs) must submit a draft facility specific implementation plan to the Safety Basis Office (for concurrence) that addresses facility categorization and subsequent safety basis document development."

  Guidance Note: These implementation plans should be consistent with any applicable UC/NNSA contract Appendix F, Performance Objectives and Measures.

- Facility safety basis requirements must be determined by the facility hazard category that is derived by implementing the requirements in LIR 300-00-05.

- Formality, rigor, and level of safety analysis will be on a graded approach commensurate with the hazards and other vulnerabilities.

- Facility safety basis will be based on the first three integrated safety management (ISM) core functions: define work in the facility, identify and analyze hazards, and establish controls.

- High hazard non-nuclear facility safety basis documentation must be reviewed annually; moderate hazard non-nuclear facility safety basis documentation must be reviewed every two years; and low hazard non-nuclear facility safety basis documentation must be reviewed every three years. The objective of these reviews is to verify that the safety basis documentation, including facility hazard categorization, accurately portrays the current facility configuration and satisfies all institutional requirements.

- Facility safety basis documentation must be under configuration and change control management.

- Hazard analysis must be based upon unmitigated scenarios within the mission of the facility.

- Development of the safety basis documents must have input and participation of the tenant or operating organizations.

- Facility safety analysis for moderate and high hazard category facilities must be reviewed for implementation of the requirements contained in this LIR and technical adequacy by the SBO, PS-4.

- All facilities with chemical hazards shall maintain a hazardous chemical inventory per LIR 402-510-01, *Chemical Management*, to assure the respective categorization remains valid. 29 CFR 1910.119, "Process safety management of highly hazardous chemicals" requires a process hazards analysis for facilities with a chemical in quantities at or above the specified threshold quantities listed in Appendix A to 29 CFR 1910.119.

- Facilities categorized as low or moderate for biological hazards shall implement the requirements contained in LIR 402-530-00, *Biological Safety (Biosafety)* for developing safety basis documentation and hazard controls. Form and content must be consistent with the requirements contained in this LIR.

- Low hazard category facilities must establish a formal material/inventory control to remain low hazard.

- The safety basis documents must be approved. The appropriate readiness review, in accordance with LIR 300-00-08, Startup/Restart of Laboratory Facilities/Activities, must be completed to validate the safety basis implementation.

- DOE O 420.1A, Facility Safety , Section 4.2, Fire Protection, is applicable to all DOE nuclear and non-nuclear facilities. Fire hazards analyses (FHA) are required for all nuclear facilities, significant new facilities, and facilities that represent unique or significant fire safety risks. The FHA will be developed using a graded approach.

- DOE O 420.1A, Facility Safety, Section 4.4, Natural Phenomena Hazard Mitigation, is applicable to all DOE nuclear and non-nuclear facilities. The natural phenomena hazards (NPHs) assessment will be conducted commensurate with a graded approach and commensurate with the potential hazard of the facility For hazardous facilities, the safety analyses must the ability of SSCs and personnel to perform their intended safety functions under the effects of natural phenomena. The general public, the workers, and the environment are to be protected from the impact of all natural phenomena hazards. Where no specific requirements are specified, model building codes or national consensus industry standards will be used.

7.2 Special Considerations

7.2.1 Biological Facilities

The risk assessment requirements for biological facilities are prescribed by the Centers for Disease Control (CDC) and Prevention and the National Institute of Health (NIH) and are contained in *Biosafety in Microbiological and Biomedical Laboratories,* http://www.cdc.gov/od/ohs/biosfty/bmbl/bmbl-1.htm. The development of the safety basis document must be controlled by the format and content contained in this LIR. While the BMBL provides specific guidance in terms of hazards from biological agents, demonstration of completeness will require a hazards analysis of all hazards associated with the facility. Delineation of the complete hazards set and demonstration of required controls derivation regardless of the source will be essential components of the safety basis requirements of this LIR.

> **Guidance Note:** Additional LANL requirements for biosafety are contained in LIR 402-530-00, *Biological Safety (Biosafety).*

7.2.2 Explosives Facilities

The safety basis for all explosives facilities must consist of a process hazards analysis as defined by 29 CFR 1910.119, "Process safety management of highly hazardous chemicals" [Ref. 8] if the explosive is a chemical in quantities at or above the specified threshold quantities listed in Appendix A to 29 CFR 1910.119. Approval authorities must be as defined in Section 8..

Those facilities with explosives hazards must also satisfy the requirements in:

- LIR 402-550-01.0, Explosives,
- DOE O 420.1A, Facility Safety, Section 4.1.2, Explosives Safety, and
- DOE M 440.1-1, *DOE Explosives Safety Manual*.

7.2.3 Multiple Hazard Facilities

The safety basis requirements must be in accordance with those defined for the dominant hazard.

> **Guidance Note:** For example, there could be a situation where the consequences due to chemical hazards exceed the consequences associated with explosives in a facility. In that case, the safety basis requirements are established in accordance with the chemical categorization. However, the requirements of DOE M 440.1-1 would still apply to the explosives hazards.

The exemption from the requirements of 10 CFR 830, Subpart B, "Nuclear Safety Management", because the facility inventory is less than the STD 1027-92 hazard category 3 threshold quantities, will not relieve the facility from conducting analysis where required to evaluate potential radiation exposures to workers.

8.0 IMPLEMENTATION REQUIREMENTS FOR SAFETY BASIS DEVELOPMENT

The developer of the safety basis will work closely with the line organizations that perform the work and with the SBO, PS-4, throughout the development of the safety basis.

Guidance Note: Certain exceptions for explosives have been made in Section 7.

8.1 Office Facility

8.1.1 Safety Basis

Office facilities are **not** required to have safety basis documentation. Office facilities are within the integrated safety management (ISM) program. The hazards present in an office facility are adequately addressed by ISM, though a Facility Safety Plan is not required.

8.2 Low Hazard Facility

8.2.1 Safety Basis

The safety basis of a low hazard non-nuclear facility consists of an Facility Safety Plan (FSP) based on ISM processes. The facility safety plan must provide for a formal hazard control to inventory and account for hazardous chemicals to ensure that the facility does not inadvertently enter a higher hazard category.

Biological low hazard facilities must additionally implement the safety basis documentation requirements contained in LIR 402-530-00.

8.3 Moderate Hazard Facility

8.3.1 Safety Basis

Safety basis for a moderate hazard non-nuclear facility will require more extensive analysis and review than for low hazard facilities because of the potential impact on uninvolved workers. A formal safety basis will consist of a facility safety analysis (FSA) and OSR using the following required content:

1. **Site Description**. Briefly describe the LANL site, location of the facility, other facilities located in the vicinity, and any major hazards of natural phenomena and external events associated with the facility (e.g., meteorology, seismology, and flood plains).
2. **Description of Facility and Operations**. The facility and associated operations and activities are described in detail to provide a full description of the facility structure, engineered systems, process, and support activities.
3. **Hazard Analysis (HA).** A comprehensive HA of activities associated with the facility is performed and documented for all FSA. The HA includes the effect of natural phenomena and external events that apply to the facility. Additionally, the HA must include those unique hazards that must be controlled from a worker safety perspective. ISM directly addresses worker safety in the development of work control documents and

generally, laboratory quantities of chemicals might not be considered unique. However, in implementing this requirement, consideration must be given to identifying what would be considered unique versus standard industrial (thus controlled by ISM processes). This process is intended to clearly identify that facility equipment that should be treated as ML-2.

> **Guidance Note:** Use of the methodology in OST 300-00-06, Safety Basis Handbook, Section 1, *Hazard Analysis Technical Methodology Handbook* is encouraged and will facilitate consistency, quality, and timeliness in gaining approval of the FSA.

4. **Hazard Controls.** The highest consequence accidents must be evaluated to determine the hazard controls that are most important. Those hazard controls that protect against permanent or life-threatening injury to uninvolved workers are identified as Management Level 2 (ML-2). Determination of ML-2 controls results from the HA as well as sound engineering judgment of the safety analysts. Mechanisms for ensuring that these important ML-2 controls are effective must be described in the OSRs. Hazard controls for facility and involved workers must be implemented through the ISM processes/safety management programs for those hazards that are considered standard industrial and may result in ML-2 controls. Controls for unique mission related hazards, must be identified in the HA and treated as ML-2.
5. **Safety Management Programs**. The safety management programs (SMPs) that are important for safety of the workers, public, and the environment must be described.

   > **Guidance Note**: The bulk of these programs are described in LA-UR-98-2837, *Integrated Safety Management Description Document* and the Laboratory institutional requirements as described in LPRs and LIRs. For applicable safety management programs, reference to these documents and a statement of commitment should be sufficient; repeating the information found in these documents should be avoided.

   Any approved deviations or exceptions to these requirements must be included in the description.

   In addition, the FSA must include a brief discussion, including required references, of any additional facility-specific programs that are important, but are not included in the Laboratory ISM description document, LPRs, or LIRs.

6. **Operational Safety Requirements.** The safety basis must include facility OSRs that may be documented in the FSA as a separate chapter or in a separate document. OSRs must include the formal commitments to engineered systems, administrative controls, and safety management programs required to ensure that the ML-2 hazard controls derived in the HA are implemented.

DOE O 420.2B, *Safety of Accelerator Facilities*, requires a safety analysis document (SAD) to be developed for accelerator facilities. This SAD must follow the content provided for a

moderate hazard facility, above, or, if different content is used, the SAD must contain a matrix or crosswalk to show full implementation of the above content.

8.3.2 Authorizing Individual(s)

For moderate hazard facilities, the RDL must review and forward safety basis documentation to the responsible AD for approval via the SBO, PS-4. The SBO will conduct an independent review to verify the adequacy of the technical analysis, as well as selection and effectiveness of the hazard controls. After successful review and resolution of comments, the SBO will forward the safety basis documents to the responsible AD recommending approval. The AD will approve the safety basis.

An accelerator facility SAD must be reviewed in a manner similar to that of a moderate hazard safety basis document; however, the SAD must be forwarded by the AD to NNSA/LASO for approval.

The approval authority for a biological facility at the level of BSL-3 must be negotiated with NNSA. The documentation must clearly demonstrate that the unmitigated release of bioagents cannot result in serious or lethal offsite consequences; otherwise, the facility must be considered a high hazard facility and the approval authority must be NNSA/LASO.

8.3.3 Safety Basis Change Control

Change control must address maintaining the operations within the facility safety basis. Moderate hazard facilities must implement a formal change control program. Change control must be graded commensurate with the facility hazards, complexity, and life-cycle status and state the level of approval of planned changes determined to be outside the approved safety basis.

On a frequency not to exceed two years from final approval or the most recent revision, the RDL must perform a full safety basis review. As a result of the review, the SB documentation must be updated and include authorized changes made within the Safety Basis Change Control Program and submitted to the required AD via the SBO, PS-4, for approval.

8.4 High Hazard Facility

8.4.1 Safety Basis

Safety basis documentation for a high hazard facility will be more extensive and detailed than that for moderate hazard facility. In addition to the safety basis requirements contained in Section 8.3.1, the high hazard FSA must include:

1. **Site Description**. No additional requirements.
2. **Description of Facility and Operations**. Safety SSC relied upon to mitigate consequences to the public must be described in greater detail with emphasis on safety functions and support systems required to be operable in order for the safety SSC to carry out its safety function.

3. **Hazard Analysis (HA).** In addition to the qualitative HA, the high hazard facility FSA will require a quantitative accident analysis for those hazard scenarios with the highest potential consequences to the public to determine the bounding, unmitigated consequences.
4. **Hazard Controls**. Controls added to mitigate the consequences to the public below ERPG 3 must be classified as ML-1.
5. **Safety Management Programs**. No additional requirements.
6. **Operational Safety Requirements.** A higher level of quality and formality will be applied to SSCs graded ML-1 for safety including defining operability and periodic inspections to demonstrate this operability.

8.4.2 Authorizing Individual(s)

For high hazard facilities, the NNSA/LASO must be the safety basis approval authority. The safety basis, including the FSA and OSR, must undergo an institutional and independent review by the SBO, PS-4, before submitting the documents to NNSA for approval. The independent review must verify that the technical analysis meets the established requirements and the hazard controls are sufficient to protect the worker and the public. After successful review and resolution of comments, the SBO will recommend acceptance of the documents to the RDL who then must forward the document to the NNSA for approval.

8.4.3 Safety Basis Change Control

A formal change control program to review and examine changes in operation, process, hardware, software, and procedures for impacts to the safety basis must be established and implemented for high hazard facilities. Change control will be graded commensurate with facility hazards, complexity, and life-cycle status and also states the level of approval of planned changes that are determined to be outside that which is described in the approved safety basis.

On a frequency not to exceed one year, the RDL must perform a review of the safety basis, and considering authorized changes made within the Safety Basis Change Control Program and update the documentation as required.

Requests to NNSA for changes to safety basis documents must meet the following requirements:

- Change requests will be based only on the currently approved documents.
- Complete, exact page changes will be provided (i.e., all pages that contain changes including pagination, renumbering, etc. exactly as these pages are to be issued once approved).
- All technical and text changes will be clearly and consistently marked on the baseline document and submitted in addition to the exact page changes identified above.

8.5 New Facilities, Facility Upgrades or Modifications, and Special Projects

8.5.1 Preliminary Hazard Analysis

As required by LIR 300-00-05 and LIR 220-01-01, *Construction Project Management*, the hazard categorization of new facilities and facility upgrades or modifications must be determined during the conceptual phase of the project and documented initially in the preliminary hazard analysis (PHA) to support a Critical Decision (CD)-1 milestone.

> **Guidance Note:** Guidance for preparing the preliminary hazard analysis (PHA) is found in Section 1 of the Safety Basis Handbook.

8.5.2 Preliminary Facility Safety Analysis

The preliminary FSA will be an input to the design process for new moderate and high hazard category facilities or facility upgrades/modifications. A draft preliminary FSA must be prepared to support a CD-2 milestone. Because this document supports the preliminary design input, the preliminary FSA will focus on identifying safety SSC and hazard controls including safety function and functional requirements. The preliminary FSA must be developed to support the CD-3 milestone.

> **Guidance Note:** As an input document in the design definition stages, the emphasis of the preliminary FSA is to provide definition to safety SSC, both active and passive engineer-design features, rather than SMP and administrative controls. The format and content of the preliminary FSA should follow Section 8.3 and 8.4, as required.
>
> **Guidance Note:** The above requirement for preliminary FSA is not specifically reflected in LIR 220-01-01.
>
> **Guidance Note:** NNSA specifies the approval authority required for the safety basis associated with these projects and these same requirements apply to special projects for which NNSA and LANL jointly agree require special NNSA authorization.

8.6 Facility Safety Plans, Facility Tenant Agreements, and Authorization Agreements

The safety basis must be documented, either directly or by reference, in the FSP.

> **Guidance Note**: The FSP implementation requirements are found in LA-UR-98-2837, Section 5.5, LPR 240-01-00, and LIG 240-01-10, *Facility Safety Plan*.

8.7 Training

The RDL must ensure that trained and competent personnel prepare and manage the safety basis and related processes. Competence will be based on the experience of the individual and the

individual's knowledge of the facility, activities, process and mission, safety basis documents, relevant LIRs and standards, and hazard and accident analysis methodologies.

The leader of the SBO, PS-4, must ensure that the qualifications of SBO personnel involved in the review of safety basis documents are relevant to the task assigned in the review.

The division leader for a tenant organization will train the facility workers in the safety basis and hazard controls and to use only controlled copies of the safety basis and hazard control documents in facility operations.

8.8 Reporting of Abnormal Events

Facility conditions that are found to be outside of the safety basis for the facility must be reported in accordance with the requirements contained in LIR 402-130-01, *Abnormal Events.*

9.0 DOCUMENTATION

9.1 Documentation Owner

The Office of Institutional Coordination (OIC) for developing, revising, and maintaining this document will be the SBO, PS-4, phone number 505-665-0513.

9.2 Distribution

Emergency Management and Response (EM&R) will be provided with a copy of the FSAs at the 90% completion milestone and a controlled copy of all approved FSAs and FSPs.

> **Guidance Note**: EM&R reviews these documents to determine applicability of an emergency planning hazard assessment in accordance with LIR 403-01-01, *LANL Emergency Management*. In addition, a controlled copy of the DSA is maintained at the Emergency Operations Center.

9.3 References

1. 10 CFR 830, "Nuclear Safety Management"
2. 29 CFR 1910.119, "Occupational Safety and Health Standards"
3. DOE M 440.1-1, *DOE Explosives Safety Manual*
4. DOE O 420.2B, *Safety of Accelerator Facilities*
5. DOE STD 1027-92 (Change Notice 1, Sept. 1997), *Hazard Categorization and Accident Analysis Techniques for Compliance with DOE Order 5480.23, Nuclear Safety Analysis Reports*
6. EMPIP 240 (LANL), *Emergency Management Plan Implementing Procedures – Protective Action Guides*
7. HHS Publication No. (CDC) 93-8395, "Biosafety in Microbiological and Biomedical Laboratories"
8. LA-UR-98-2837, *Integrated Safety Management Description Document*
9. LIG 230-01-02, *Graded Approach for Facility Work*

10. LIG 240-01-10, *Facility Safety Plan*
11. LIR 220-01-01, *Construction Project Management*
12. LIR 230-03-01, *Facility Management Work Control*
13. LIR 230-04-01, *Laboratory Maintenance Management Program*
14. LIR 240-01-01, *Facility Configuration Management*
15. LIR 300-00-01, *Safe Work Practices*
16. LIR 300-00-02, *Documentation of Safe Work Practices*
17. LIR 300-00-05, *Facility Hazard Categorization*
18. LIR 402-510-01, *Chemical Management*
19. LIR 402-530-00, *Biological Safety (Biosafety)*
20. LIR 402-130-01, *Abnormal Events*
21. LIR 403-00-01, *Los Alamos National Laboratory Emergency Management*
22. LPR 240-01-00, *Facility and Operating Limits and Configuration*
23. OST 300-00-06, Safety Basis Handbook, Section 1, *Hazard Analysis Technical Methodology Handbook*
24. US Department of Health and Human Services, Centers for Disease Control, “Biosafety in Microbiological and Biomedical Laboratories,” 4th Edition, May 1999
25. LIR 300-00-08, Startup/Restart of Laboratory Facilities/Activities
26. IMP 352.0, Project Management